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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/738,446	KELLY ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 39-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 14-20, 33-35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0104800 to Collins et al.

In the specification and figures, Collins discloses the apparatus substantially as claimed by applicant. With regard to claims 14, 33-35 Collins discloses a hemodiafiltration apparatus comprising a medical fluid circuit 40, medical fluid supply 50, first pump 62 to supply medical fluid to filtration apparatus 10, second pump 44 operable to pull fluid from the filtering device, and isolating apparatus in the form of upstream and downstream valves 51, 55 (see FIG 1a, paragraphs 0037-0039). The device further comprises a control unit 110 that uses control schemes to operate the valves and pumps (see paragraph 0042). The controller may operate to close valves 51, 55 in order to place the cartridge in isolation or bypass mode and command pump 62 to deliver a volume of substitute fluid to the patient (see paragraph 0045).

The control scheme disclosed by Collins uses a second, separate replacement fluid supply 300 to deliver a bolus volume to the patient. The Examiner notes, however, that the fluid in reservoir 300 originated in supply 50, which means that the reservoir 300 contains fluid from the first fluid supply. Collins merely uses an intermediate storage

location 300 for fluid from supply 50. Accordingly, when in isolation mode, substitution pump 62 delivers a volume of fluid that was originally from fluid supply 50.

In the alternative to the interpretation presented above, it is the position of the Examiner that the source of the fluid delivered by the bolus is a matter of design choice on the part of the Applicant. Collins discloses that both reservoirs 50 and 300 comprise diasylate fluid, rendering the operation disclosed by Collins functionally equivalent to the operation claimed by Applicant. Applicant has not disclosed that using the same medical fluid supply for both filtration and bolus is for any particular purpose or solves any particular problem. (Arguments of counsel do not comprise objective evidence.) The process disclosed by Collins is the functional equivalent of the process claimed by applicant. Accordingly, it is the position of the Examiner that merely providing a single source of fluid for filtration and bolus as disclosed by Applicant rather than separate sources, as disclosed by Collins, is not a patentable difference from the apparatus disclosed by the cited prior art.

With regard to claim 15, Collins discloses that the volume of fluid issued to the patient is a bolus volume issued to maintain proper patient fluid balance, meeting the limitations of the claims (see paragraph 0045).

With regard to claim 16, Collins discloses that the control scheme is programmed to receive user input before delivery of the bolus (see paragraph 0045).

With regard to claims 17-18 regarding the bolus volume entered by the operator (17) and that the bolus volume is predetermined prior to therapy (18), Applicant's recitation with regard to the operation of the controller is not a positive structural

limitation and only sets forth what the controller is capable of doing when prompted by an operator. Apparatus claims cover what a device is, not what it does. See MPEP § 2114. In the instant case, Collins discloses that the apparatus may provide a specified bolus volume (see paragraph 0045). There is no language in the claims regarding the actual function of the device; the claims set forth a method of operating and programming the device. Accordingly, it is the position of the examiner that the Collins device is capable of being used by an operator to control the pumps and valves as claimed by applicant, thereby meeting the limitations of the claim.

With regard to claims 19 and 20, Collins discloses that the control scheme relies on input from various pressure and flow sensor devices (such as a blood flow sensor which corresponds to applicant's blood volume sensor) in delivery of the bolus volume (see paragraphs 0011, 0045).

With regard to claim 38, Collins discloses that the apparatus may comprise a temperature sensor, wherein the control scheme is programmed to halt the first pump 62 if the rate of temperature decay exceeds a certain value (see paragraph 0011).

3. Claims 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0104800 to Collins et al in view of US 5,932,103 to Kenley et al.

In the specification and figures, Collins discloses the device substantially as claimed by applicant (see rejection above).

With regard to claims 21, 23, and 26, Collins fails to disclose that the bolus delivered to the patient comprises a rinseback volume delivered at the end of therapy. Kenley discloses a dialysis system configured to allow postdilution (see column 51, lines

14-20) that also uses dialysis fluid as a rinseback fluid that is communicated to the patient after the completion of therapy upon patient input as controlled by the valves, pumps, and optical sensors (see column 48, lines 1-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to program the system disclosed by Sternby to deliver a rinseback fluid to the patient after therapy, as disclosed by Kenley, in order to ensure all extracorporeal blood is returned to the patient.

With regard to claim 22, Kenley discloses that the rinseback procedure is performed automatically, without manual operator input. It has been held that the elimination of an element and its function is obvious if the element is not desired. See MPEP § 2144.04(II)(A). It is the position of the Examiner that the removal of automatic control from the apparatus suggested by Collins and Kenley is merely the removal of an undesired element (automation) and its function (automatic control). Accordingly, applicant's claim drawn to a manual operator input is an unpatentable variation of the prior art.

With regard to claims 24 and 25, Applicant recites the operation of the controller. Such limitations are considered by the examiner to lack positive structural limitations, and only set forth what the controller is capable of doing when prompted by an operator. Apparatus claims cover what a device is, not what it does. See MPEP § 2114. There is no language in the claims regarding the actual function of the device; the claims set forth a method of operating and programming the device. In the instant case, it is the position of the examiner that the devices disclosed by the prior art are substantially

structurally similar to the claimed device and are capable of being programmed to either function with operator input or automatically as claimed by applicant, thereby meeting the limitations of the claim.

With regard to claims 27, 29, and 32, Collins fails to disclose that the bolus delivered to the patient comprises a prime volume delivered at the beginning of therapy. Kenley discloses a dialysis system configured to allow postdilution (see column 51, lines 14-20) that also uses dialysis fluid as a priming fluid that is communicated through the circuit before therapy as controlled by the valves, pumps, and air detectors of the circuit (see column 47, line 50 to column 46, line 27).

With regard to claim 28, Kenley discloses that the rinseback procedure is performed automatically, without manual operator input. It has been held that the elimination of an element and its function is obvious if the element is not desired. See MPEP 2144.04(II)(A). It is the position of the Examiner that the removal of automatic control from the apparatus suggested by Collins and Kenley is merely the removal of an undesired element (automation) and its function (automatic control). Accordingly, applicant's claim drawn to a manual operator input is an unpatentable variation of the prior art.

With regard to claims 30 and 31, Applicant recites the operation of the controller. Such limitations are considered by the examiner to lack positive structural limitations, and only set forth what the controller is capable of doing when prompted by an operator. Apparatus claims cover what a device is, not what it does. See MPEP 2114. There is no language in the claims regarding the actual function of the device; the claims set forth a

method of operating and programming the device. In the instant case, it is the position of the examiner that the devices disclosed by the prior art are capable of being programmed to either function with operator input or automatically as claimed by applicant, thereby meeting the limitations of the claim.

4. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0104800 to Collins et al in view of WO 99/29355 to Sternby.

In the specification and figures, Collins discloses the device substantially as claimed by applicant (see rejection above).

With regard to claim 36, Collins fails to disclose that the device may be configured to alternately deliver fluid to the extracorporeal circuit either upstream of downstream of the blood filtering device in a single embodiment. However, Sternby illustrates that the device may be configured for upstream delivery in the embodiment shown in FIG 3, and downstream delivery in the embodiment shown in FIG 4. Taken together, the disclosures reasonably suggest to one of ordinary skill in the art both upstream and downstream bolus lines, providing both predilution and postdilution capability in a single configuration. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add an upstream medical fluid delivery line to the apparatus disclosed by Collins in order to allow for predilution and postdilution in a single configuration.

With regard to claim 37, Collins fails to disclose that the medical fluid flow path comprises a line to remove ultrafiltrate upstream from the bolus delivery point. Sternby

illustrates that the medical fluid flow path may comprise a drain line 12 to remove ultrafiltrate upstream of the location 21 in which medical fluid is delivered to the extracorporeal blood circuit in order to prevent fluid overload in the line (see FIG 4). Accordingly, it would have been obvious to one having ordinary skill in the art at the time of invention to add to the Collins device a drain line upstream of the bolus delivery point as disclosed by Sternby in order to prevent fluid overload in the line.

Response to Arguments

5. Applicant's amendment and arguments filed 25 July 2008 have been entered and fully considered.

6. Applicant's arguments with respect to the rejection(s) of claim(s) 14-20, 33-35, and 38 under 35 USC § 103(a) to Collins have been fully considered but are not persuasive.

7. Applicant argues that Collins' delivery of a fluid bolus volume from a discrete source of fluid 300 than fluid supply 50 provides advantages such as removing unnecessary equipment from the apparatus, removing the need to sterilize and maintain extra reservoirs and tubing lines. Applicant argues that such a substantial reduction in hardware and control complexity is not a matter of mere design choice. The Examiner respectfully disagrees. The solution in container 300 disclosed by Collins originates from fluid supply 50. As such, fluid pumped from container 300 is part of the fluid pumped from supply 50, so that when Collins pumps fluid from reservoir 300 into the circuit, it originates in supply 50, meeting the limitations of the claims. Furthermore,

arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., In re Huang, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). Applicant has presented no objective evidence that the removal of the reservoir and tubing disclosed by Collins results in a clinically significant reduction of tubing infection and failure. As such, it is the position of the Examiner that the system disclosed by Collins reasonably suggests the apparatus claimed by Applicant.

8. Applicant further argues that if valve 55 in Collins is opened to deliver fluid from supply 50 to the circuit, the filter is no longer isolated. The Examiner agrees with this point, and the rejection has been amended to exclude such a suggestion.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
30 September 2008